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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,160	10/08/2003	David M. Goldenberg	018733-1236	5791

26633 7590 09/08/2005

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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,160

Applicant(s)

GOLDENBERG, DAVID M.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-89 is/are rejected.
- 7) ☒ Claim(s) 90 and 91 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/10/05</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

1. Claims 82-91 are pending.
2. In view of the amendment filed 6/10/05, the following rejection remains.
3. Claims 82-89 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 91 of copending Application No. 10/206,361. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 91 of copending application 10/206,361 recites a method for treating a mammal having either a multidrug resistant tumor that expresses a tumor associated antigen or a multidrug resistant disease caused by an infectious agent, said method comprising the steps of (I) administering an antibody composite to said mammal, wherein said antibody composite

comprises:

(a) at least one antibody component that binds with a first epitope of a multidrug transporter protein, and

(b) at least one antibody component that binds with a first epitope of an antigen, wherein said antigen is associated with said tumor or said infectious agent, wherein said antibody components are selected from the group consisting of

(i) a murine monoclonal antibody,

(ii) a humanized antibody derived from (i),

(iii) a human monoclonal antibody,

(iv) a subhuman primate antibody and

(v) an antibody fragment derived from (i), (ii), (iii) or (iv); wherein said antibody fragment is selected from the group consisting of F(ab')₂, F(ab)₂, Fab', Fab, Fv, sFv and minimal recognition units; wherein said multidrug transporter protein is selected from the group consisting of P-glycoprotein, OtrB, Tel(L), Mmr, ActII, TcmA, NorAs, QacA, CmlA, Bcr, EmrB, EmrD, AcrE, EnvD, MexB, Smr, OacE, Mvrc, MsrA, DrrA, DrrB, Tlrc, Bmr, TetA and OprK;

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(II) administering a therapeutic agent to said mammal. wherein said therapeutic agent is selected from the group consisting of cancer chemotherapeutic drug, antiviral drug, antifungal drug, antibacterial drug and antiprotozoal drugs and

(III) administering an immunomodulator to said mammal wherein said immunomodulator is selected from the group consisting of cytokine, stem cell growth factor and hematopoietic factor, wherein said immunomodulator is administered subsequent to said administration of said antibody composite (species).

Although the claims are not identical, the binding specificity of the antibody composite (polyspecific antibody) in the claimed method of instant application is the same as the claim 91 of copending application 10/206,361. Further, copending claim 91 of 10/206,361 is species claim to the genus claims of the instant application and therefore anticipates the claimed invention. An issuance of a patent to instant application would include the claimed subject matter of 10/206,361.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that applicant will consider appropriate action to address this rejection when the claims are indicated as allowable in copending application 10/206,361.

4. Claims 90-91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

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action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
8. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

September 2, 2005


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600